

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Determining the effect of low-power laser therapy on midline laparotomy pain compared to placebo in upper and lower gastrointestinal surgeries

Protocol summary

Study aim

Our aim of this study is to evaluate the effect of low-power laser therapy as a complementary treatment to reduce midline laparotomy wound pain.

Design

This clinical trial with parallel control and intervention group, double-blind, randomized groups, after obtaining written consent on 100 patients who are candidates for midline laparotomy for elective surgery ; will start. The online software www.randomizer.org was used for randomization.

Settings and conduct

Laser irradiation will be done for each patient of intervention group for 6 minutes during the first three days after the operation. first dose of radiation will be done after recovery and in the ward, and the next doses will be done at intervals of 24 hours until the third day after the operation in It will be done in hospitalization at Tehran Baqiyatallah hospital. same number of sessions for the control group will also be done with a turned off device.

Participants/Inclusion and exclusion criteria

In this study,100 patients (ASA I-II) with the age range of 30 to 60 years who are candidates for midline laparotomy for elective surgery of the upper and lower gastrointestinal tract were included in the study, and by lack of satisfaction, they will be excluded from the study.

Intervention groups

The first group (control) receives the usual treatments after the operation, including intravenous and oral painkillers in case of pain, in addition to being treated with an OFF low-level laser, and the second group (study) in addition to receiving the treatments of the group First, they are treated with an ON low-level laser.

Main outcome variables

The main outcome variables of this study are evaluation the amount of pain at the midline laparotomy surgery site, the amount of serum inflammatory factors, the amount of local wound complications, in addition to

assessment the amount of pain-reducing drugs in both intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056225N1**

Registration date: **2022-11-27, 1401/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-27, 1401/09/06**

Update count: **0**

Registration date

2022-11-27, 1401/09/06

Registrant information

Name

hamed gholizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of low-power laser therapy on midline laparotomy pain compared to placebo in upper and lower gastrointestinal surgeries

Public title

Efficacy of Low Level Laser Therapy on The Post Midline laparotomy Wound Pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are in the age range of 30 to 60 years. Patients who underwent midline laparotomy were selected for elective upper and lower gastrointestinal surgery.

Exclusion criteria:

Patients who do not agree to participate in the study. Patients who, in addition to surgery, have other serious medical problems (ASA III-VI) or suffer from psychotic disorders or drug addiction.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

By Using the online software www.randomizer.org, the patients were divided into two groups of 50 people, control and intervention, in a simple and individual way. Considering that the study is double-blind; The patient and the attending physician as pain evaluators will not know whether the patients belong to the control or intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and pain evaluators, as well as the researcher of this study, by considering that the randomization of patients is done by the intervention provider, are not aware of which patient received the intervention and which patient received the placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Baqiyatallah Hospital

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Baqiyatallah University of Medical Sciences, Baqiyatallah hospital, Department of General Surgery, Azam Ave, South Sheikh Bahai St, Molla Sadra Blvd, Vanak Square, Tehran

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1435915371

Approval date

2022-06-24, 1401/04/03

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.029

Health conditions studied**1****Description of health condition studied**

Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code

K42

ICD-10 code description

Umbilical hernia

2**Description of health condition studied**

Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code

K43

ICD-10 code description

Ventral hernia

3**Description of health condition studied**

Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code

K46

ICD-10 code description

Unspecified abdominal hernia

4

Description of health condition studied

Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code

K31

ICD-10 code description

Other diseases of stomach and duodenum

5

Description of health condition studied

Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

Primary outcomes

1

Description

Midline laparotomy surgery site pain

Timepoint

Before beginning of the intervention, 24, 48, 72 hour's after beginning of the intervention

Method of measurement

visual analogue scale

2

Description

Local complications of the laparotomy site

Timepoint

Before beginning of the intervention, 24, 48, 72 hour's after beginning of the intervention

Method of measurement

Inspection of the operation site

3

Description

serum Inflammatory factors

Timepoint

Before beginning of the intervention, 24, 48, 72 hour's after beginning of the intervention

Method of measurement

Taking daily blood tests

Secondary outcomes

1

Description

The amount of painkillers

Timepoint

Before beginning of the intervention, 24, 48, 72 hour's after the start of the intervention

Method of measurement

check the patient's medical record

Intervention groups

1

Description

Intervention group: In addition to receiving the treatments of the first group, the intervention group is also treated with low-power laser. The distance of 2 cm from the wound after removing the surgical dressing will be 0.5 J/cm² radiation dose. Considering that the radiation cross-section was considered to be 30 square centimeters; According to the formula $t = (D \cdot A) / P$, the radiation time was calculated for 6 minutes each time. In total, the laser radiation will be done during the first three days after the operation for each patient, and its sequence will be such that the first dose of radiation It will be done after recovery and in the ward, and the next doses will be done at 24-hour intervals until the third day after the operation while in the hospital.

Category

Treatment - Devices

2

Description

Control group: The first group (control) after the operation receive the usual treatments, including intravenous and oral pain relievers in case of pain, in addition to being treated with a low-power silent laser (Placebo). In total, during the first three days after After the operation, each patient will be treated with placebo three times, and the sequence will be such that the first time will be done after recovery and in the ward, and the next times will be done at intervals of 24 hours until the third day after the operation while in the hospital. will be done.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Hosein Samadinia

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Baqiyatallah University of Medical Sciences, Baqiatallah hospital, Department of General Surgery, Azam Ave, South Sheikh Bahai St, Mollasadra Blvd,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abbas Ali Imanifooladi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Madadi Emamchai

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data of this study according to the plan and after the completion of the data analysis so that the patients under study are not identifiable can be received by contacting the person in charge of scientific accountability in case of decision to publish the article in the ICMJE-related journals.

When the data will become available and for how long

The access period starts 6 months after the publication of the article in ICMJE-related journals.

To whom data/document is available

All researchers of university institutes who have published articles in ICMJE-related journals will be able to access the information of this study.

Under which criteria data/document could be used

The data and analysis results of this study can only be used for inclusion in review studies.

From where data/document is obtainable

To receive the data or the results of the analysis of this study, please refer to the person responsible for the scientific response of this study, Mr. Dr. Mohammad Madadi Imamchai, with the following contact information. Address: Baqiyatallah University of Medical Sciences, Department of General Surgery, Azam Ave, South Sheikh Bahai St, Molla Sadra Blvd, Vanak Square, Tehran. Mobile number: 00989104009204 Workplace phone number: 00982181267609 Fax number: 00982188033539 Email: geniusman68@yahoo.com Postal code: 1435915371

What processes are involved for a request to access data/document

The request of receive information can be processed in a period of less than one week after checking the mentioned necessary conditions.

Comments